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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,489	10/16/2003	Jeffrey M. Linnen	GP140-04.UT	3927
21365	7590	01/27/2006	EXAMINER	
GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE SAN DIEGO, CA 92121			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 01/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,489

Applicant(s)

LINNEN ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-26, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-25, 29 and 30 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/27/05</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet.</u> |

Continuation of Attachment(s) 6). Other: Petition Decision -Change of Inventorship.

DETAILED ACTION

1. Claims 18-26, 29, and 30 are pending in the application.
2. In the prior action, mailed on May 4, 2005, claims 18-30 were pending and rejected. In the Response submitted on October 28, 2005, the Applicant amended claims 18 and 29; and cancelled claims 27 and 28.
3. Currently, claims 18-26, 29, and 30 are pending and under consideration. The claims read on primers for the amplification of nucleic acid sequences in the 3' untranslated region of West Nile virus. The Applicant elected the species wherein the primers comprise SEQ ID NOs: 75 and 64.
4. Because of the new grounds of rejection (the restatement of prior 112 rejections), the rejection is made Non-Final.

Inventorship

5. In view of the papers filed October 28, 2005, the inventorship in this nonprovisional application has been changed by the deletion of Reinhold Pollner, Wen Wu, Geoffrey G. Dennis, and Paul M. Darby.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Information Disclosure Statement

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6. The information disclosure statements (IDS) submitted on July 25, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Restated and Maintained)** Claims 18-30 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the primer pairs according to claim 26, or primer pairs wherein the first primer comprises 22 contiguous bases with SEQ ID NO: 74 and the second primer is one of those listed (as opposite strand primers) in Table 14 (page 58), does not reasonably provide enablement for amplification kits comprising any primer comprising 22 bases from SEQ ID NO: 74, any primer comprising 18 bases of SEQ ID NO: 59, or any related sequence varying from such sequence by inclusion of a nucleotide analog or up to 10% base variation. The claims have been amended to exclude embodiments wherein the primers may include nucleotide analogs or up to 10% base differences. Further, the claims have been amended to require that the first primer comprises 22 contiguous bases of SEQ ID NO: 74 (encompassing the operable primers of SEQ ID NOs: 75-77). Thus, the amendments have overcome the rejection of record. The rejection is withdrawn from claim 26, as this claim defines allowable subject matter. The rejection is also withdrawn from claims 27 and 28, which have been cancelled from the application.

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However, upon further review of the application, it is noted that the application teaches that the operability of the primers consisting of fragments of SEQ ID NO: 74 in combination with a primer consisting of a fragment of SEQ ID NO: 59 represents an unexpected result in view of the failures seen using other combinations of primers. See e.g., pages 58-59 of the application. Such results indicate an inherent unpredictability in the claimed invention. In view of this unpredictability, the indication that primers comprising other sequences than those specifically disclosed were not operative, and a lack of any structural feature that correlates to the presence or absence of the ability of the primer combinations to work, the present claims appear to exceed the scope of enablement provided by the application. In particular, the claims are rejected because they read on primers comprising sequences in addition to those shown to be operative. See e.g., claim 18 (requiring only that the primers comprise the operative sequences), and claims 19 and 20 (permitting the use of primers of up to 60 or 35 bases including the operative sequences). In view of the disclosure of the application that the use of sequences other than those disclosed resulted in kits that were not capable of detecting viral sequences, the claims are rejected to the extent that they permit the inclusion of such additional sequences.

9. Thus, while the application is enabling for the claimed kits wherein the first primer consists of an optional first upstream sequence not complementary to the target sequence and a second target-complementary sequence that consists of 22-24 bases of SEQ ID NO: 74, and a second primer that consists of an optional first upstream sequence not complementary to the target sequence and a second target-complementary that consists of 18-22 residues of SEQ ID NO: 59, the claims are not so limited and are therefore rejected for the reasons indicated above. The rejection is therefore maintained over claims 18-25, 29, and 30.

10. **(Prior Rejection- Restated and Maintained in part)** Claims 18-30 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims have been described above. The rejection is withdrawn from claim 26, as this claim defines allowable subject matter. The rejection is also withdrawn from claims 27 and 28, which have been cancelled from the application. The rejection is maintained over claims 18-25, 29, and 30.

In the prior action, the claims were rejected as claiming a genus of primer combinations for which there was insufficient written description support. The rejection specifically referred to the inclusion of nucleoside analogs and sequences that varied from those in the application up to a certain percent identity. However, consideration of the same factors described in the prior action further indicates that the current claims still exceed the genus for which adequate description was provided. In particular, the rejection is restated and maintained over the claims to the extent that they permit the inclusion of target-complementary sequences other than those specifically shown to work.

As indicated in the prior action, the application indicates that only a limited set of primer combinations were able to operate in kits such as those claimed. See esp., pages 58-59 of the application. As the application does not provide any structural means for distinguishing between those primers that are operative and those that are not, and as the application teaches that inclusion of sequences other than those disclosed resulted in inoperative embodiments, the application has not provided adequate descriptive support for a genus of operative primer pairs

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comprising the indicated sequence as part of a larger primer comprising 35, 60, or more bases with other non-complementary sequences.

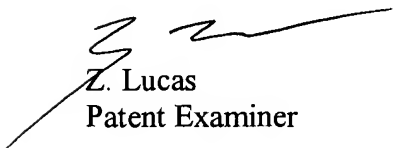
Conclusion

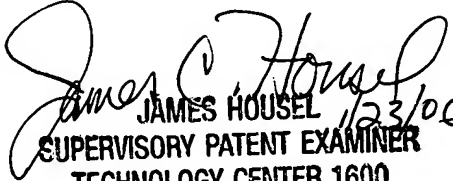
11. No claims are allowed. Claim 26 is objected to as depending from a rejected claim.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 1/23/06
SUPERVISORY PATENT EXAMINER
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